MAY 1 4 2012

# 510(k) Summary

**Date Prepared:** May 9, 2012

**510(k) Number:** K113266

## Submitter's Name / Contact Person


**Manufacturer**
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: 763-656-4300; Fax: 763-656-4250
Establishment Registration # 2134812

**Contact Person**
Jennifer Ruether
Sr. Regulatory Product Specialist


## General Information

| | |
|---|---|
| **Trade Name** | Gel-Block Embolization Pledgets |
| **Common / Usual Name** | Device, vascular, for promoting embolization |
| **Classification Name** | 870.3300; KRD; vascular embolization device; Class II |
| **Predicate Devices** | K991549: Embosphere Microspheres (BioSphere Medical, Inc.)<br>K052742: QuadraSphere Microspheres (BioSphere Medical, Inc.) |

## Device Description

The Gel-Block Embolization Pledgets are an embolic device consisting of two radially-compressed gelatin pledgets that can be delivered through a catheter system. The pledgets are stored individually within a transparent delivery assembly that has a luer lock on the proximal end and a vented cap on the distal end. The luer lock allows for attachment to syringes for flushing, while the vented cap allows the flushing to occur without pledget evacuation from the delivery assembly. After flushing, the vented cap is removed to expose a threaded luer that connects to the hub of an in-place delivery catheter.

The Gel-Block Embolization Pledgets consist of the following components:

- Two gelatin pledgets, in individual delivery assemblies
- One syringe for pledget delivery

## Intended Use / Indications

The Gel-Block Embolization Pledgets are intended for use in embolization of hypervascularized tumors and arteriovenous malformations (AVMs).

## Technological Characteristics

The Gel-Block Embolization Pledgets are similar in design to the predicate devices, as all of them provide a mechanical barrier to blood flow in the vasculature and are delivered using catheters. The ability of the Gel-Block to swell is similar to that of the QuadraSpheres. The subject device is available in three consistent sizes, while the predicates are available in defined size ranges. The subject and predicate devices also differ in shape; because the Gel-Block Pledgets are larger than the predicate microspheres, they are cylindrical in shape for easy delivery through a catheter. The Gel-Block Embolization Pledgets also differ from both predicate devices in terms of materials, and therefore degradation; the Embospheres consist of a non-resorbable acrylic polymer impregnated with porcine gelatin, while the Gel-Block is made wholly from resorbable porcine gelatin. The QuadraSpheres consist of a sodium acrylate-vinyl alcohol co-polymer.

The technological differences between the subject and predicate devices have been evaluated through biocompatibility, bench, and animal testing to provide evidence of safe and effective use of the Gel-Block Embolization Pledgets, thereby establishing substantial equivalence to the predicate devices.

## Substantial Equivalence and Summary of Studies

The Gel-Block Embolization Pledgets are substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use. The device design has been verified through the following tests:

- Swelling capability
- Pepsin digestibility
- Flushing capability
- Deliverability
- Formaldehyde residuals

Biocompatibility was verified through the following test strategy compliant with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute systemic toxicity
- Subchronic toxicity
- Genotoxicity
- Hemocompatibility
- Implantation

A GLP animal study was conducted on nine test and four control (Embosphere Microspheres) adult female sheep over a period of 12 weeks. Angiography and/or histopathology confirmed that the Gel-Block Embolization Pledgets provided an embolic effect in renal arteries for at least four weeks. All test animals had renal infarct indicative of successful embolization for a duration similar to that of the control animals. There were no observed incidents of non-targeted embolization in nearby vessels. No signs of systemic toxicity were observed. Anemia was observed in four test animals. However, *in vitro*

hemocompatibility testing did not produce evidence of significant hemolysis, thus mitigating this concern.

Results of the design verification, animal study, and biomaterial tests did not raise new safety or performance questions and support the substantial equivalence of the Gel-Block Embolization Pledgets to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

MAY 14 2012

Vascular Solutions, Inc.
c/o Jennifer Ruether
Senior Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, MN 55369

Re: K113266
Trade/Device Name: Gel-Block Embolization Pledgets
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: March 19, 2012
Received: March 20, 2012

Dear Ms. Ruether:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K113266

Device Name: Gel-Block Embolization Pledgets

Indications for Use:

The Gel-Block Embolization Pledgets are intended for use in embolization of hypervascularized tumors and arteriovenous malformations (AVMs).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113266


*(Posted November 13, 2003)*